

Guide to Completing the Clinical Research Protocol Roles in iRIS

The key study personnel roles in iRIS have been unified with the study roles recognized by the NIH (1195 form). The names and definitions of the NIH-accepted roles are listed below, and additional instructions are included to assist staff in understanding how to apply each role in the protocol and in iRIS.

NIH Investigators who appear on the Face Sheet of the protocol should be assigned one of the first 4 roles on the list. These individuals are subject to conflict of interest rules and DEC review. The Medical Advisory Investigator, Lead Associate Investigator, and Associate Investigator roles can be assigned to staff who are entered in the Additional Investigators section of the Key Study Personnel. These personnel can be assigned additional roles (e.g., Accountable Investigator, Research Contact) in the Research Staff Section, but should be included as an AI if their name appears on the Face Sheet of the protocol.

In addition, two roles that are exclusive to iRIS function and that allow for the administrative processing of protocols and actions by the applicable staff are also defined.

NIH Defined Roles

Principal Investigator (PI): PIs must be NIH employees and responsible for designing, conducting and monitoring protocols, ensuring the protection of human subjects, overseeing the informed consent process and the integrity and analysis of research data, including prevention of conflicts of interest by all associate investigators on their protocols. PIs assure that protocols are followed and that data are collected promptly and accurately. They are responsible for ensuring that necessary approvals are obtained. There is only one principal investigator for each protocol. PIs must be qualified members of the credentialed CC senior, junior, research or adjunct staff, registered nurses, pharmacologists, psychologists, or other health professionals. Consultants, contractors, and students may not act as principal investigators.

Medical Advisory Investigator (MAI): Assists in the development of the clinical aspects of the protocol and advises the PI on clinical matters. An MAI must be identified when the PI is not a member of the Junior or Senior Staff, or when the Clinical Director, IRB, or Director, CC, consider it warranted. The MAI must be a member of the CC Junior or Senior Medical Staff.

An MAI should be used if the PI is not credentialed at the NIH Clinical Center, such as a nurse (non-nurse practitioner), pharmacist, or allied health professionals.

The MAI role should not be used for a Medical Monitor.

Lead Associate Investigator (LAI): an individual who played a leading role in the formulation, writing, and implementation of a clinical research protocol under the mentorship of the protocol's principal investigator. A lead associate investigator may be a physician, a dentist, a Ph.D., an RN, a member of the allied health professions, or a trainee.

At the present time, the LAI role is the same as our Protocol Chairperson role and was designed primary to recognize the contributions of fellows who can not serve as a PI. Lead Associate Investigator will replace Protocol Chairperson on NCI protocols in updated protocol template guidelines and iRIS updates.

Associate Investigator(s) (AI): an individual(s), other than the PI, API, MAI or LAI, who makes substantial contributions to the conception and design of the study, or to the acquisition of data, or to the analysis and interpretation of data. There may be several AIs on a protocol.

Please note: contract data managers should not be included as Associate Investigators and should not be listed on the protocol Face Sheet.

Accountable Investigator: tenured or tenure-track investigator or senior clinicians who are responsible and accountable for the scientific quality and expenditure of resources for the protocol. In some Institutes, the Accountable Investigator is the Branch Chief or Department Head.

Please note, for CCR protocols, in most cases, the PI is the Accountable Investigator. This role should only be assigned in iRIS if the Accountable Investigator is a different individual than the PI.

Adjunct Principal Investigator (API): an individual serving as the principal investigator who is not an NIH employee. If the protocol has an Adjunct Principal Investigator, there must be a named NIH Principal Investigator who is an employee and who will be responsible for the conduct and conflicts analysis of the protocol. The relationship between the Adjunct PI and the NIH PI will allow for the conduct of collaborative protocols between the intramural and extramural/outside medical community.

Research Contact: the individual(s) to whom the Patient Recruitment and Public Liaison (PRPL) Office refers potential participants who have questions about the protocol.

This role should be used to identify branch referral coordinators or offices. The Office of the Clinical Director will assist in establishing an e-mail box for such an office.

IRIS Specific Roles (These individuals will not be listed on the Protocol Face Sheet)

In addition to the roles listed above, the following roles are used in iRIS in an administrative capacity:

Study Coordinator: this role allows for study set up, completion of forms, and submission of all forms in iRIS. This role is designed for Branch protocol support office personnel or for a research team member who processes the team's protocol actions. More than one individual can be assigned to this role (e.g. Branch-specific protocol support office and the research nurse may all be assigned study coordinator role in iRIS).

Study Contact: this role will receive all correspondence sent from iRIS regarding all protocols actions. The Study Contact can not submit forms in iRIS. iRIS defaults this role to the PI, but the PI can be removed from this role if desired (the PI will also receive all correspondence on protocol actions in iRIS). The lead research nurse on the protocol could also be the Study Contact. More than one individual can be assigned to this role (e.g. Branch-specific protocol support office, the research nurse and a 3rd year fellow in the LAI role may all be assigned the study contact role in iRIS).